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EXAMINER	
REDDIG, PETER J	

ART UNIT	PAPER NUMBER
1642	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/603,006	YOUNG ET AL.	
	Examiner	Art Unit	
	Peter J. Reddig	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31 and 33-36* is/are pending in the application.

4a) Of the above claim(s) *9-31 and 33-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 January 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/09 & 3/19 2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The response filed on May 1, 2006 to the restriction requirement of March 17, 2006 has been received. Applicant has elected Group I, claims 1-8 for examination without traversal.

Claims 1-31 and 33-36 are currently pending.

Claims 9-31 and 33-36 have been withdrawn by applicant.

Claims 1-8 are currently under examination.

Examiner has established a priority date of June 23, 2003 for the instantly claimed serial number 10/603,006 because the claims as currently constituted recite "delaying disease progression" and a review of the parent applications does not reveal the claimed limitation. Applicant is invited to submit evidence pointing to the serial number, page and line where support can be found establishing an earlier priority date.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). The claimed subject matter that does not have antecedent basis in the specification is the method of delaying disease progression or the limitation "identifying characteristics" of a monoclonal antibody encoded by a clone deposited with the ATCC as accession number PTA-4890.

Because the claims as filed in the original specification are part of the disclosure, even though the material disclosed in the claims is not disclosed in the remainder of the specification, the applicant may amend the specification to include the claimed subject matter. In re Benno, 768 F.2d 1340, 226 USPQ 683 (Fed. Cir. 1985). Thus amendment of the specification to include the material disclosed in the claims will obviate this objection.

Appropriate correction is required.

Specification Objections

2. The amendment filed February 2, 2004, is objected to under 35 U.S.C. § 132 because it introduces new matter into the specification. 35 U.S.C. § 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

This application is a continuation-in-part of application S.N. 10/348.231, filed January 21, 2003, the contents of which are herein incorporated by reference.

Applicant amends the specification and states that no new matter is added. However, a review of the filing papers reveals that the newly claimed priority document is mentioned in none of the Declaration as originally filed or the originally filed transmittal papers. Thus, the amendment to the specification to revise the claimed priority is new matter.

Applicant is required to cancel the new matter in the response to this Office action.

3. The drawings are objected to because the amended Figure 7, received January 23, 2004, adds new matter. Applicant argues on p. 3, 2nd para., in remarks made with the amendment received January 23, 2004, that the treatment period began 21 days post-implantation of PC-3 prostate cancer cells. Further the applicant argues that the administration was discontinued at 43 days post-implantation. The treatment period, as demarcated by the dashed lines, in the amended Figure 7 appears to be from abut 17 days post-implantation to 35 days post-implantation. Although argued by applicant, applicant doest not point to support in the specification for the amendment and review of the specification did not reveal support for the amendment.

Applicant is required to cancel the new matter in the response to this Office action.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing

sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-8 are indefinite because claim 1 recites the phrase "identifying characteristics". The claims are indefinite because the specification provides no definition of "identifying characteristics". Thus it is not possible to determine if the identifying characteristics of the claimed product used in the claimed method are drawn to the product's characteristics as a

monoclonal antibody, as a protein, as a binder to a particular antigen, or as a binder to a cancer cell. Given the above, the metes and bounds of the subject matter claimed cannot be determined and neither the specification nor the claims as originally filed particularly points out or distinctly claims the subject matter which applicant regards as the invention.

Claim 5 recites the limitation "the method of claim" wherein no claim is specified. There is insufficient antecedent basis for this limitation in the claim. Thus the metes and bounds of the claim protection sought cannot be determined.

Claim 8 is indefinite because it recites the phrase a "chimerized antibody". The exact meaning of the word chimera is not known. The term chimera is generic to a class of antibodies which are products of genetic shuffling of antibody domains and other active proteins. The term encompasses antibodies fused to non-immunoglobulin proteins as well as antibodies wherein any domain of the antibody is substituted by corresponding regions or residues of human antibodies including but not limited to CDR grafted antibodies. Thus the metes and bounds of the claim protection sought cannot be determined.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of extending survival and delaying disease progression by treating a human tumor in a mammal, wherein said tumor expresses an antigen which

specifically binds to a monoclonal antibody or antigen binding fragment thereof which is encoded by a clone deposited with the ATCC as accession number PTA-4890 comprising administering to said mammal said monoclonal antibody in an amount effective to reduce said mammal's tumor burden, whereby disease progression is delayed and survival is extended, does not reasonably provide enablement for a method of extending survival and delaying disease progression by treating a human tumor in a mammal, wherein said tumor expresses an antigen which specifically binds to a monoclonal antibody or antigen binding fragment thereof which has the **identifying characteristics** of a monoclonal antibody encoded by a clone deposited with the ATCC accession number PTA-4890 comprising administering to said mammal said monoclonal antibody in an amount effective to reduce said mammal's tumor burden, whereby disease progression is delayed and survival is extended. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in *In re* Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to:

the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill, the level of predictability in the art, the amount of direction provided by the inventor, the existence of working examples, and the quantity of experimentation needed to make or use the invention based on the content of the disclosure. See also *Ex parte* Forman, 230 USPQ 546 (BPAI 1986).

The claims are drawn to a method of extending survival and delaying disease progression by treating a human tumor in a mammal, wherein said tumor expresses an antigen which specifically binds to a monoclonal antibody or antigen binding fragment thereof which has the **identifying characteristics** of a monoclonal antibody encoded by a clone deposited with the ATCC accession number PTA-4890 comprising administering to said mammal said monoclonal antibody in an amount effective to reduce said mammal's tumor burden, whereby disease progression is delayed and survival is extended (PTA-4890 is also denoted in the specification as 7BD-33-11A (para. bridging pp. 18-19). This means that the method of treating a human tumor in a mammal depends on a monoclonal antibody which has the **identifying characteristics** of an antibody encoded by a clone deposited with the accession number PTA-4890 (herein referred to as PTA-4890 for simplicity).

The specification teaches that PTA-4890 is a monoclonal antibody, p. 19, lines 1-9. Further, the specification teaches that PTA-4890 was obtained following immunization of mice with cells from a patient's breast tumor biopsy, p8. lines 2-4. Furthermore, the specification teaches that the PTA-4890 antigen is detected in several cell types and in the normal tissue of the salivary gland, liver, pancreas, stomach, prostate, duodendum, and the tonsil and no other normal tissues examined (p. 11, lines 15-20). The PTA-4890 antigen staining by immunohistochemistry was displayed in both the membrane and cytoplasm, (p. 12, line 2). The PTA-4890 antigen was not detected in normal breast tissue and was found in 36 % of breast tumor tissue samples (p. 12, lines 3-11). The PTA-4890 antigen staining in staged tumor samples suggested a trend towards greater positive expression with higher tumor stage, although the sample size was limited (p12, lines 21-22). Several other human tumor types expressed the PTA-4890 antigen including skin,

lung, liver, stomach, thyroid, prostate, uterus, and kidney. Greater staining was seen on malignant cells of the skin, lung, liver, uterus, kidney, stomach and bladder (p. 13, lines 3-8). The antigen to which PTA-4890 binds was not taught in the specification

One cannot extrapolate the teaching of the specification to the scope of the claims because there is insufficient guidance and direction as to how to make and use antibodies which have the identifying characteristics of monoclonal antibody PTA-4890 because they are being defined by, among other things, an unknown antigen.

The courts have found that definition of an antibody by binding to an unknown is not enabling. In particular, the court teaches as follows: "Noelle did not provide sufficient support for the claims to the human CD40CR antibody in his '480 application because Noelle failed to disclose the structural elements of human CD40CR antibody or antigen in his earlier '799 application. Noelle argues that because antibodies are defined by their binding affinity to antigens, not their physical structure, he sufficiently described human CD40CR antibody by stating that it binds to human CD40CR antigen. Noelle cites En zo Biochem II for this proposition. This argument fails, however, because Noelle did not sufficiently describe the human CD40CR antigen at the time of the filing of the '799 patent application. In fact, Noelle only described the mouse antigen when he claimed the mouse, human, and genus forms of CD40CR antibodies by citing to the ATCC number of the hybridoma secreting the mouse CD40CR antibody. If Noelle had sufficiently described the human form of CD40CR antigen, he could have claimed its antibody by simply stating its binding affinity for the "fully characterized" antigen. Noelle did not describe human CD40CR antigen. Therefore, Noelle attempted to define an unknown by its binding affinity to another unknown. As a result, Noelle's claims to human

forms of CD40CR antibody found in his '480 application cannot gain the benefit of the earlier filing date of his '799 patent application. Moreover, Noelle cannot claim the genus form of CD40CR antibody by simply describing mouse CD40CR antigen". *Randolph J. Noelle v Seth Lederman, Leonard Chess and Michael J. Yellin* (CAFC, 02-1187, 1/20/2004).

To reiterate, applicant is claiming antibodies against an unknown and since an antibody is defined by its antigen binding capability, claims drawn to unknown antibodies that bind to unknown antigens are not enabled. The specification provides insufficient guidance with regard to these issues and provides no working examples which would provide guidance to one skilled in the art and no evidence has been provided which would allow one of skill in the art to predictably make or use the broadly claimed antibodies with a reasonable expectation of success. For the above reasons, it appears that undue experimentation would be required to practice the claimed invention.

8. If applicant were able to overcome the above rejection set forth above, Claims 1-6 and 8 would still be rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of extending survival and delaying disease progression wherein said tumor expresses an antigen which specifically binds to a monoclonal antibody or antigen binding fragment thereof which has the identifying characteristics of a monoclonal antibody encoded by a clone deposited with the ATCC accession number PTA-4890 comprising administering to said mammal said monoclonal antibody in an amount effective to reduce said mammal's tumor burden, whereby disease progression is delayed and survival is extended, wherein said antibody is a humanized antibody, does not reasonably provide while being enabling for a method of

extending survival and delaying disease progression wherein said tumor expresses an antigen which specifically binds to a monoclonal antibody or antigen binding fragment thereof which has the identifying characteristics of a monoclonal antibody encoded by a clone deposited with the ATCC accession number PTA-4890 comprising administering to said mammal said monoclonal antibody in an amount effective to reduce said mammal's tumor burden, whereby disease progression is delayed and survival is extended, wherein said antibody is a murine antibody. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims read on treating a human tumor in a mammal with a mouse monoclonal antibody PTA-4890. This means the claims read on, and the specification contemplates, the treatment of cancer in humans with antibodies produced in a mouse.

Factors to be considered in determining whether undue experimentation is required, are summarized in *In re* Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to:

> the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill, the level of predictability in the art, the amount of direction provided by the inventor, the existence of working examples, and the quantity of experimentation needed to make or use the invention based on the content of the disclosure. See also *Ex parte* Forman, 230 USPQ 546 (BPAI 1986).

The specification teaches using substantially the process of US 6,180,370, the mouse monoclonal antibody PTA-4890 was obtained following immunization of mice with cells from a

patient's breast tumor biopsy, p8, lines 2-4. Further the specification teaches that these antibodies can be used to treat tumor metastases, p.8, lines 6-7.

One cannot extrapolate the teachings of the specification to the scope of the claims because Winter et al (TIPS, 1993, 14:139-143) specifically teach that a major problem with the use of murine monoclonal antibodies in the treatment of human subjects is the development of human antimouse antibodies (HAMA) that can inactivate the injected antibodies. Thus, it would be expected that the injection of cross species antibody would result in anti-other species antibodies and/or cytotoxic T cells against the injected antibody. Further, Baselga et al (J. Clin. Oncol, 1996, 14:737-744) specifically teach that murine antibodies are limited clinically because they are immunogenic.

Given the above, it is clear that it is not possible to predict that a mouse monoclonal antibody PTA-4890 would successfully treat a human tumor in a human as contemplated in the specification. Thus it would require undue experimentation to practice the broadly claimed invention.

9. If applicant were able to overcome the above rejection set forth above, Claims 1-8 would still be rejected under 35 U.S.C. 112, first paragraph, because the specification, for while being enabling for delaying disease progression as measured by the parameter of preventing body weight loss in prostate cancer by treating a human tumor in a mammal with a monoclonal antibody which has the identifying characteristics of PTA-4890, does not reasonably provide enablement for delaying all parameters of disease progression in any cancer. The specification

does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in *In re* Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to:

the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill, the level of predictability in the art, the amount of direction provided by the inventor, the existence of working examples, and the quantity of experimentation needed to make or use the invention based on the content of the disclosure. See also *Ex parte* Forman, 230 USPQ 546 (BPAI 1986).

The specification teaches that in the PC-3 SCID mouse xenograft model body weight can be used as a surrogate indicator of disease progression (p. 10, lines 17-18). In this model the specification teaches that at day 52 of engraftment the PTA-4890 monoclonal antibody treated mice had significantly higher body weight than the control group and that PTA-4890 prevented body weight loss by 54%. After discontinuation of treatment with PTA-4890, the mice survived greater than three times longer than the control mice (Example 3,p. 23, lines 1-8, Fig. 5 & 6). Table 2 teaches that metastatic breast cancer cells do not express or significantly express the antigen bound by PTA-4890.

One cannot extrapolate the teaching of the specification to the scope of the claims because there is insufficient guidance in the disclosure for delaying disease progression by administering PTA-4890 to a mammal with a human tumor. Those of skill in the art for example, Tannock and Hill, recognize that cancer progression is defined as the tendency of

tumors to become more malignant as they grow, p. 399 (Tannock, I. F. and Hill, H. P., The Basic Science of Oncology, 1992). However nothing in the specification indicates that the treatment delays the progression to metastases. Tannock and Hill teach that malignancy is the essential property of cancer cells that is demonstrated by their ability to proliferate indefinitely, to invade surrounding tissue, and to metastasize to other organs, p. 399. Additionally, Tannock and Hill teach that the metastatic cell must establish new growth at its new location in the organism, Ch. 11, Section 11.2.6. Thus, progressed, metastatic tumor cells must proceed through multiple steps to affect the host by establishment and growth of cells at a distal site. Tannock and Hill teach assays which measure metastasis by enumerating the ability of tumor cells to establish new growth at distal sites through direct or indirect counting of the number of ectopic growths, Section 11.3.1 and Figure 11.8. However, neither the specification nor the art of record teaches that the administration of PTA-4890, in fact, delays metastasis. In fact, it appears from Table 2 that in order to metastasize, the tumor cells must lose expression of the antigen bound by PTA-4890. Given the above it is not clear how treatment with PTA-4890 could effectively delay progression as understood by those of skill in the art.

Applicant is reminded that MPEP 2164.03 teaches "the amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability of the art. In re Fisher, 428 F.2d 833, 166 USPQ 18, 24 (CCPA 1970) the amount of guidance or direction refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly state in the

specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as how to make and use the invention in order for it to be enabling. Given only lack of guidance in the specification, no one skilled in the art would accept the assertion that the claimed invention would function as contemplated or as claimed based only on the information in the specification and that known in the art at the time the invention was made.

The specification provides insufficient guidance with regard to these issues and provides no working examples which would provide guidance to one skilled in the art and no evidence has been provided which would allow one of skill in the art to predict that the invention will function as contemplated with a reasonable expectation of success. For the above reasons, it appear that undue experimentation would be required to practice the claimed invention.

10. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-8 are broadly drawn to a method of extending survival and delaying disease progression by treating a human tumor in a mammal, wherein said tumor expresses an antigen which specifically binds to a monoclonal antibody or antigen binding fragment thereof, comprising administering a monoclonal antibody which has the identifying characteristics of a monoclonal antibody encoded by a clone deposited with the ATCC as accession number PTA-4890. It is noted that the antigen to which PTA-4890 binds has not been characterized other than

to note that the antibody binds to an antigen in a number of tissues, thus, other than localization of binding, no identifying characteristics of a monoclonal antibody encoded by a clone deposited with the ATCC as accession number PTA-4890 are known. Although drawn to DNA arts, the findings in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and Enzo Biochem, Inc. V. Gen-Probe Inc. are relevant to the instant claims. The Federal Circuit addressed the application of the written description requirement to DNA-related inventions in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The court stated that "[a] written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." Id. At 1567, 43 USPQ2d at 1405. The court also stated that

> a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA" *without more, is not an adequate* written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.

Id. At 1568, 43 USPQ2d at 1406. The court concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id.

Finally, the court addressed the manner by which a genus of cDNAs might be described. "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a

recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." Id.

The Federal Circuit has recently clarified that a DNA molecule can be adequately described without disclosing its complete structure. See Enzo Biochem, Inc. V. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court adopted the standard that "the written description requirement can be met by 'show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics.... i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." Id. At 1324, 63 USPQ2d at 1613 (emphasis omitted, bracketed material in original).

The inventions at issue in Lilly and Enzo were DNA constructs per se, the holdings of those cases are also applicable to claims such as those at issue here. A disclosure that does not adequately describe a peptide antigen product itself logically cannot adequately describe an antibody to that antigen product.

Thus, the instant specification may provide an adequate written description of the antibody with identifying characteristics of PTA-4890 useful for extending survival and delaying disease progression, per Lilly by describing "structural features common to the members of the genus, which features constitute a substantial portion of the genus". Alternatively, per Enzo, the specification can show that the claimed invention is complete "by disclosure of sufficiently detailed, relevant identifying characteristics, functional characteristics when coupled with a

known or disclosed correlation between function and structure, or some combination of such characteristics."

In this case, the specification does not describe monoclonal antibodies with identifying characteristics useful for extending survival and delaying disease progression in a manner that satisfies either the Lilly or Enzo standards. The specification does not provide the complete structure of identifying characteristics of the claimed antibody other than localization in various tissues, nor does the specification provide any partial structure of such identifying characteristics, nor any physical or chemical characteristics of the said identifying characteristics nor any functional characteristics coupled with a known or disclosed correlation between structure and function. Although the specification discloses that the antigen to which ATCC clone PTA-4890 specifically binds is expressed in various normal tissues (p11, 3rd para. and Example 5) and tumor types (p. 12-13 and Example 6), this does not provide a description of the identifying characteristics of the claimed antibody.

The specification also fails to describe the identifying characteristics by the test set out in Lilly. Therefore, it necessarily fails to describe a "representative number" of such species. In addition, the specification also does not describe "structural features common to the members of the genus, which features constitute a substantial portion of the genus."

Thus, the specification does not provide an adequate written description of the claimed identifying characteristics of the monoclonal antibody PTA-4890 that are required to practice the claimed invention. Since the specification fails to adequately describe the identifying characteristics of the claimed antibodies useful for extending survival and delaying disease

progression by treating a human tumor in a mammal, it also fails to adequately describe the claimed method.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described *in a printed publication in this or a foreign country or in public use or* on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1, 6, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Cobleigh et al. (Journal of Clinical Oncology, 1999, 17:2639-2648).

Given the indefinite claim language drawn to "identifying characteristics" as set forth above, it is assumed for examination purposes that the identifying characteristics of the PTA-4890 *includes a monoclonal antibody which binds breast tumor tissue antigens.*

The claims are drawn to a method of extending survival and delaying disease progression by treating a human tumor in a mammal, wherein said tumor expresses an antigen which *specifically binds to a monoclonal antibody or antigen binding fragment thereof,* comprising administering a monoclonal antibody which has the identifying characteristics of a monoclonal antibody encoded by a clone deposited with the ATCC as accession number PTA-4890 (Claim 1), wherein said antibody is a murine antibody (Claim 6), wherein said antibody is a humanized antibody (Claim 7).

Cobleigh et al. teach treating metastatic breast cancer in women with a humanized, murine anti-HER2 monoclonal Herceptin, antibody that delayed progression and increased survival (see Materials and Methods-Tumor Response, p.2640, right column; p. 2641, left

column to p. 2642 left and right column; and Fig. 1), wherein the monoclonal antibody binds to breast cancer cells and thus shares identifying characteristics with PTA4890. All of the limitations of the claims are met.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cobleigh et al. (Journal of Clinical Oncology, 1999, 17:2639-2648), in view of Goers et al. (US Patent No., 4,867,973, September 19, 1989), in further view of Dillman (Annals of Internal Medicine, 1989; 111:592-603), and in further view of Hellstrom et al. (PNAS, 1986, 83:7059-7063).

The claims are drawn to a method of extending survival and delaying disease progression by treating a human tumor in a mammal, wherein said tumor expresses an antigen which specifically binds to a monoclonal antibody or antigen binding fragment thereof, comprising administering a monoclonal antibody which has the identifying characteristics of a monoclonal antibody encoded by a clone deposited with the ATCC as accession number PTA-4890 (Claim 1), wherein said antibody is conjugated to a cytotoxic moiety (Claim 2), and wherein said cytotoxic moiety is a radioactive isotope (Claim 3), wherein said antibody activates complement (Claim 4), wherein said antibody mediates antibody dependent cellular cytotoxicity (Claim 5).

Cobleigh et al. teach treating metastatic breast cancer in women with a humanized anti-HER2 monoclonal antibody that delayed progression and increased survival (see Materials and Methods-Tumor Response, p.2640, right column; p. 2641, left column to p. 2642 left and right column; and Fig. 1). Cobleigh et al. does not teach that the antibody conjugated to a cytotoxic moiety, wherein said cytotoxic moiety is a radioactive isotope, and wherein said antibody activates complement, wherein said antibody mediates antibody dependent cellular cytotoxicity.

Further Hellstrom et al. teach the use of a specific subclass of mouse monoclonal antibody, subclass IgG2a or IgG3, has the advantages of mediating complement mediated cytotoxicity and antibody dependent cellular cytotoxicity (p.7059, left column and abstract). Further, Hellstrom et al. teach that these antibody isotypes can be selectively isolated (p.7059, right column). Further, Goers et al. teach the successful conjugation of cytotoxic moieties to antibodies (column 6), the use of radioactive isotopes as the cytotoxic moiety (column 19 and Table 1), and the successful use of these agents against tumors (Column 14) and Dillman teaches that due to the limited efficacy of monoclonal antibodies alone in clinical treatments, cytotoxic immunoconjugates are employed (p. 595, left column). Dillman also teaches that the radiolabeled immunoconjugates are the technically easiest to make (p. 595, right column).

Thus, the state of the art at the time the invention was made not only included the knowledge of treating human tumors in a mammal with a monoclonal, humanized antibody with the identifying characteristics of a *monoclonal* antibody encoded by a clone deposited with the ATCC as accession number PTA-4890, but also that the prior art teaches using a specific subclasses of mouse monoclonal antibodies, IgG2a or IgG3, has the advantage of mediating antibody-dependent cellular cytotoxicity and activating complement and these isotypes can be selectively isolated, and that antibodies could easily be conjugated to radioactive cytotoxic moieties to successfully improve treatment. Thus one of ordinary skill in the art would have had motivation and a reasonable expectation of success in making and using the claimed invention.

Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi* , 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 1-8 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10-16 of Patent No. 7,009,040.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they relate to the same inventive concept. The instant claims are generic to the claims of the copending application and would have been obvious in view of the copending claims.

The instantly claimed method is generic to the method of patent 7,009,040 which is drawn to a method of treating human breast and prostate tumors susceptible to antibody induced cellular cytotoxicity in a mammal, wherein said human breast and prostrate tumors express an antigen which specifically binds to the monoclonal antibody encoded by a clone deposited with the ATCC as accession number PTA-4890 or a cellular cytotoxicity inducing antigen binding fragment thereof, comprising administering to said mammal said monoclonal antibody or said

antigen binding fragment thereof in an amount effective to induce cellular cytotoxicity and thereby reduce said mammal's tumor burden (Claim 10), the method of claim 10 wherein said monoclonal antibody is conjugated to a cytotoxic moiety (Claim 11), the method of claim 11 wherein said cytotoxic moiety is a radioactive isotope (Claim 12), the method of claim 10 wherein said monoclonal antibody activates complement (Claim 13), the method of claim 10 wherein said monoclonal antibody mediates antibody dependent cellular cytotoxicity (Claim 14), the method of claim 10 wherein said monoclonal antibody is humanized (Claim 15), the method of claim 10 wherein said monoclonal antibody is chimerized (Claim 16).

Given that the patented claims are a species of the instantly claimed invention, they make obvious the instantly claimed invention.

17. Claims 1-8 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 33-40 of copending Application No. 10/810,751.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they relate to the same inventive concept. The instant claims are generic to the claims of the copending application and would have been obvious in view of the copending claims.

The instantly claimed method claims the same method as that of Application No 10/810,751 which is drawn to a method of treating a human tumor in a mammal, wherein said tumor expresses an antigen which specifically binds to a monoclonal antibody or antigen binding fragment thereof which has the identifying characteristics of a monoclonal antibody encoded by

a clone deposited with the ATCC as accession number PTA-4890, comprising administering to said mammal said monoclonal antibody in an amount effective to reduce said mammal's tumor burden. (Claim 1), the method of claim 1 wherein said monoclonal antibody is conjugated to a cytotoxic moiety (Claim 2), the method of claim 2 wherein said cytotoxic moiety is a radioactive isotope (Claim 3), the method of claim 1 wherein said monoclonal antibody activates complement (Claim 4), the method of claim 1 wherein said antibody mediates antibody dependent cellular cytotoxicity (Claim 5), the method of claim 1 wherein said antibody is a murine antibody (Claim 6) the method of claim 1 wherein said antibody is a humanized antibody (Claim 7), the method of claim 10 wherein said antibody is a chimerized (Claim 8).

Given that the claims of copending Application No. 10/810,751 are a species of the instantly claimed invention, they make obvious the instantly claimed invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

18. Claims 1-8 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 56-62 of copending Application No. 10/743,451.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they relate to the same inventive concept. The instant claims are generic to the claims of the copending application and would have been obvious in view of the copending claims.

The instantly claimed method claims the same method as that of Application No 10/743,451which is drawn a method of treating a human tumor susceptible to antibody induced cellular cytotoxicity in a mammal, wherein said human tumor expressing an antigen which specifically binds to a monoclonal antibody which binds to the same epitope as the monoclonal antibody encoded by a clone deposited with the ATCC as accession number PTA-4890 or a cellular cytotoxicity inducing antigen binding fragment thereof, comprising administering to said mammal said monoclonal antibody or said antigen binding fragment thereof in an amount effective to induce cellular cytotoxicity and thereby reduce said mammal's tumor burden. (Claim 56), the method of claim 56 wherein said monoclonal antibody is conjugated to a cytotoxic moiety (Claim 57), the method of claim 57 wherein said cytotoxic moiety is a radioactive isotope (Claim 58), the method of claim 56 wherein said monoclonal antibody activates complement (Claim 59), the method of claim 56 wherein said antibody mediates antibody dependent cellular cytotoxicity (Claim 60), the method of claim 56 wherein said antibody is a humanized antibody (Claim 61), the method of claim 56 wherein said antibody is a chimerized (Claim 62).

Given that the claims are a species of the instantly claimed invention, they make obvious the instantly claimed invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

19. Claims 1-6 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6-10 of Application No. 11/370203.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they relate to the same inventive concept. The instant claims are generic to the claims of the copending application and would have been obvious in view of the copending claims.

The instantly claimed method is generic to the method of Application No. 11/370203 which is drawn to a method of treating human breast and prostate *tumors susceptible to antibody* induced cellular cytotoxicity in a mammal, wherein said human breast and prostrate tumors express an antigen which specifically binds to the monoclonal antibody encoded by a clone deposited with the ATCC as accession number PTA-4890 or a cellular cytotoxicity inducing antigen binding fragment thereof, comprising administering to said mammal a monoclonal antibody or cellular cytotoxicity inducing ligand in accordance with any one of claim 1 or 2 or 3 in an *amount* effective to induce cellular cytotoxicity and thereby reduce said mammal's tumor burden (Claim 6), the method of claim 6 wherein said monoclonal antibody is conjugated to a cytotoxic moiety (Claim 7), the method of claim 7 wherein said cytotoxic moiety is a radioactive isotope (Claim 8), the method of claim 6 wherein said monoclonal antibody activates complement (Claim 9), the method of claim 6 wherein said monoclonal antibody mediates antibody dependent cellular cytotoxicity (Claim 10).

Given that the claims are a species of the instantly claimed invention, they make obvious the instantly claimed invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

20. Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claim 56 and Claim 57 of copending Application No. 11/367,798.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they relate to the same inventive concept. The instant claims are generic to the claims of the copending application and would have been obvious in view of the copending claims.

The instantly claimed method is generic to the method of Application No. 11/367,798 which is drawn to a process for treating a human cancerous tumor which expresses human CD63 antigen comprising: administering to an individual suffering from said human cancer, at least one monoclonal antibody or ligand that recognizes the same epitope or epitopes as those recognized by the isolated monoclonal antibody produced by a hybridoma selected from the group consisting of hybridoma cell line H460-22-1 having ATCC Accession No. PTA-4622, hybridoma cell line 1A245.6 having ATCC Accession No. PTA-4889, hybridoma cell line 7BD-33-11A having ATCC Accession No. PTA- 4890, hybridoma cell line 7BDI-60 having ATCC Accession No. PTA-4623, hybridoma cell line 7BD1-58 having IDAC Accession No. 141205-01 and hybridomas cell line AR51A994.1 having IDAC Accession No. 141205-06; wherein binding of said epitope or epitopes is effective in reducing tumor burden (Claim 56),

The instantly claimed method is generic to the method of Application No. 11/367,798 which is additionally drawn to a process for treating a human cancerous tumor which expresses human CD63 antigen comprising: administering to an individual suffering from said human cancer, at least one monoclonal antibody or ligand that recognizes the same epitope or epitopes

as those recognized by the isolated monoclonal antibody produced by a hybridoma selected from the group consisting of hybridoma cell line H460-22-1 having ATCC Accession No. PTA-4622, hybridoma cell line 1A245.6 having ATCC Accession No. PTA-4889, hybridoma cell line 7BD-33-11A having ATCC Accession No. PTA- 4890, hybridoma cell line 7BD1-60 having ATCC Accession No. PTA-4623, hybridoma cell line 7BD1-58 having IDAC Accession No. 141205-01 and hybridomas cell line AR51A994.1 having IDAC Accession No. 141205-06; in conjunction with at least one chemotherapeutic agent; wherein said administration is effective in reducing tumor burden (Claim 57).

Given that the claims are a species of the instantly claimed invention, they make obvious the instantly claimed invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

21. Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claim 56 and Claim 57 of copending Application No. 11/362,452.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they relate to the same inventive concept. The instant claims are generic to the claims of the copending application and would have been obvious in view of the copending claims.

The instantly claimed method is generic to the method of Application No. 11/362,452 which is drawn to a process for treating a human cancerous tumor which expresses human CD63

antigen comprising: administering to an individual suffering from said human cancer, at least one monoclonal antibody or ligand that recognizes the same epitope or epitopes as those recognized by the isolated monoclonal antibody produced by a hybridoma selected from the group consisting of hybridoma cell line H460-22-1 having ATCC Accession No. PTA-4622, hybridoma cell line 1A245.6 having ATCC Accession No. PTA-4889, hybridoma cell line 7BD-33-11A having ATCC Accession No. PTA- 4890, hybridoma cell line 7BD1-60 having ATCC Accession No. PTA-4623, hybridoma cell line 7BD1-58 having IDAC Accession No. 141205-01 and hybridomas cell line AR51A994.1 having IDAC Accession No. 141205-06; wherein binding of said epitope or epitopes is effective in reducing tumor burden (Claim 56),

The instantly claimed method is generic to the method of Application No. 11/362,452 which is additionally drawn to a process for treating a human cancerous tumor which expresses human CD63 antigen comprising: administering to an individual suffering from said human cancer, at least one monoclonal antibody or ligand that recognizes the same epitope or epitopes as those recognized by the isolated monoclonal antibody produced by a hybridoma selected from the group consisting of hybridoma cell line H460-22-1 having ATCC Accession No. PTA-4622, hybridoma cell line 1A245.6 having ATCC Accession No. PTA-4889, hybridoma cell line 7BD-33-11A having ATCC Accession No. PTA- 4890, hybridoma cell line 7BD1-60 having ATCC Accession No. PTA-4623, hybridoma cell line 7BD1-58 having IDAC Accession No. 141205-01 and hybridomas cell line AR51A994.1 having IDAC Accession No. 141205-06; in conjunction with at least one chemotherapeutic agent; wherein said administration is effective in reducing tumor burden (Claim 57).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Given that the claims are a species of the instantly claimed invention, they make obvious the instantly claimed invention.

22. Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claim 5 and Claim 6 of copending Application No. 11/321,624.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they relate to the same inventive concept. The instant claims are generic to the claims of the copending application and would have been obvious in view of the copending claims.

The instantly claimed method is generic to the method of Application No. 11/321,624 which is drawn to a process for treating a human cancerous tumor which expresses human CD63 antigen comprising: administering to an individual suffering from said human cancer, at least one monoclonal antibody or ligand that recognizes the same epitope or epitopes as those recognized by the isolated monoclonal antibody produced by a hybridoma selected from the group consisting of hybridoma cell line H460-22-1 having ATCC Accession No. PTA-4622, hybridoma cell line 1A245.6 having ATCC Accession No. PTA-4889, hybridoma cell line 7BD-33-11A having ATCC Accession No. PTA- 4890, wherein binding of said epitope or epitopes is effective in reducing tumor burden (Claim 5),

The instantly claimed method is generic to the method of Application No. 11/321,624 which is additionally drawn to a process for treating a human cancerous tumor which expresses human CD63 antigen comprising: administering to an individual suffering from said human cancer, at least one monoclonal antibody or ligand that recognizes the same epitope or epitopes as those recognized by the isolated monoclonal antibody produced by a hybridoma selected from the group consisting of hybridoma cell line H460-22-1 having ATCC Accession No. PTA-4622, hybridoma cell line 1A245.6 having ATCC Accession No. PTA-4889, hybridoma cell line 7BD-33-11A having ATCC Accession No. PTA- 4890; in conjunction with at least one chemotherapeutic agent; wherein said administration is effective in reducing tumor burden (Claim 6).

Given that the claims are a species of the instantly claimed invention, they make obvious the instantly claimed invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

23. If applicant disagrees with any rejection set forth in this office action based on examiner's establishment of a priority date June 23, 2003 for the instantly claimed application serial number 10/603,006, applicant is invited to submit evidence pointing to the serial number, page and line where support can be found establishing an earlier priority date.

24. No claims are allowed.

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Reddig whose telephone number is (571) 272-9031. The examiner can normally be reached on M-F 8:30 a.m.-5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Peter J. Reddig, Ph.D.
Examiner
Art Unit 1642

PJR

SUSAN UNGAR, PH.D
PRIMARY EXAMINER